<u>REMARKS</u>

Claims 1 to 15, 17 to 34 and 36 are currently pending on entry of the above amendment. Claims 16 and 35 have been cancelled without prejudice or disclaimer and Applicants reserve the right to pursue the subject matter of these claims in related applications. Accordingly, no new matter has been introduced.

I. Restriction Requirement

The Examiner has required an election under 35 U.S.C. § 121 of one of the following groups:

- I. Claims 1-14, 18-34, 36 drawn to an isolated nucleic acid sequence of human PSP encoding polypeptide; vectors, host cells, and methods of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- II. Claims 15-16, 35, drawn to an isolated human PSP polypeptide and composition, comprising isolated polypeptide classified in Class 530, subclasses 300 and 350.
- III. Claim 17 drawn to isolated antibody that binds to human PSP polypeptide, classified in Class 530, subclass 387.1.

The Examiner contends that the inventions are distinct, each from the other.

In order to be fully responsive, Applicants provisionally elect, with traverse, the subject matter of Group I as represented by originally filed claims 1-14, 18-34 and 36, and drawn to polynucleotides, host cells, and methods of producing a polypeptide, for further prosecution. Applicants reserve the right to file one or more divisional applications directed to non-elected subject matter should the restriction requirement be made final. Additionally, should the present restriction requirement be made final, Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully traverse and request the withdrawal of the Restriction Requirement. As a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP \S 806.04 – \S 806.04(i)) or distinct (MPEP \S 806.05 – \S 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the groups listed by the Examiner represented distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of both groups would entail a "serious burden." *See* M.P.E.P. § 803.

In the present situation, no such showing has been made. Although the Examiner has argued that Groups I through III are separately classified, Applicants nonetheless submit that a search of the claims of Group I would also provide useful information for the claims of Group II, while a search of the claims of Group II would also provide useful information for the claims of Groups III. For example, in many if not most publications disclosing a polynucleotide, the authors also routinely include polypeptides encoded thereby. Since the searches for polynucleotides and polypeptides commonly overlap, the search and examination of a polynucleotide and the corresponding polypeptides would not entail a serious burden.

Accordingly, in view of M.P.E.P. § 803, the claims of all Groups I-III should be searched and examined in the present application. Applicants therefore respectfully request that the restriction requirement under 35 U.S.C. § 121 be reconsidered and withdrawn, and that the instant claims be examined in one application.

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II. Election of Species

The Examiner has required election of a single disclosed species for prosecution together with the identification of all claims readable thereon. In order to be fully responsive, Applicants hereby further provisionally elect, with traverse, the polynucleotide encoding the human PSP polypeptide having the amino acid sequence at positions -18 to 231 in SEQ ID NO:2, as set forth as SEQ ID NO:1 and claimed in original claim 1. The provisionally elected species is read upon by pending claims 1, 2, 10-14, and 18 as originally filed.

Applicants respectfully traverse and request the withdrawal of the requirement to elect a single species for prosecution. Applicants respectfully point out that the Examiner has not disclosed <u>any</u> statutory or regulatory basis for the further restriction within the provisionally elected Group I, or <u>any</u> reasoning or argument in support of this requirement. Applicants are simply "advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement." Applicants note that the Examiner is requiring an election of a species member of the Markush-type claims. The M.P.E.P., at § 803.02, states:

[s]ince the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas*, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozum*i, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

In the present case, Applicants contend that unity of invention among Markush group members does indeed exist. All Markush group members of the pending claims directed to the provisionally elected subject matter share a common utility, that utility being the App. No. 10/020,139

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same as that of the human parotid secretory protein of the present invention. Furthermore, these Markush group members are each derived from, and defined by reference to, the disclosed polynucleotide that encodes the human parotid secretory protein, and therefore they share "a substantial structural feature disclosed as being essential to that utility."

In addition, MPEP § 803.02 further requires that "[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits." Applicants contend that the members of the Markush groups found in the pending claims to provisionally elected Group I are sufficiently few in number and very closely related, as they are all different *portions of the same polynucleotide sequence*, so that a search of all of the members may be made without a serious burden. Moreover, even assuming that examination of the entire claim would present a serious burden, MPEP § 803.02 states that "[f]ollowing election, the Markush-type claim will be examined fully as to the elected species and further to the extent necessary to determine patentability." If no prior art is found "that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended." *Id.* (emphasis added).

Accordingly, Applicants respectfully request that the restriction requirement under 35 U.S.C. § 121 and the further requirement for election of species within Group I be withdrawn and the instant claims be examined in one application.

Applicants respectfully request that the above-made amendment and remarks be entered and made of record in the file history of the instant application.

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<u>CONCLUSION</u>

In view of the foregoing remarks, applicants believe that this application is now in condition for substantive examination. The Examiner is invited to call the undersigned at the phone number provided below if any further action by applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: July 15, 2002

in J. Hymel (Reg. No. 45,414)

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Enclosures MMW/LJH/BM/lcc